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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,812	11/12/2003	Chang Yi Wang	1151-4175	5762

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,812	WANG ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/5/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group I, species M peptides Seq ID Nos. 5-6, in the reply filed on 4/29/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-7 and 11 have been examined to the extent that they read upon the elected species.

Priority

No claim has been made for domestic or foreign priority, so the effective date for this application is the same as the filing date, November 11, 2003.

Claim Rejections - 35 USC § 112

Claims 4-6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 11 recite "immunologically functional analogues." The specification defines "immunologically functional analogues" on page 9 as "modified...yet retains substantially the same secondary and tertiary structure and/or immunogenicity as the original SCoV antigenic peptide." Claim 1 explicilty recites SEQ ID NO:6 as an "immunologically functional analogue", and claim 4 explicilty recites "an altered charge" as a type of "immunologically functional analogue." However, on considering page 31 of the specification, it is apparent that addition of three lysine residues to SEQ ID NO:5 (to create SEQ ID NO:6) substantially changes

the antigenic properties (albeit in a beneficial manner). Therefore, one of the embodiments identified as an "immunologically functional analogue" violates the requirement of the definition that it retain substantially the same immunogenicity of the original peptide. Consequently, it is not clear what the recitation "immunologically functional analogue" really means, and it is unclear what materials are encompassed by the claims.

Claims 1-3 are not included in the above rejection, because the recitation "immunologically functional analogues thereof" is followed by "selected from the group consisting of SEQ ID NO....". Although it may be unclear what constitutes an "immunologically functional analogue," the Markush group is clear and definite.

Claims 4-6, 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, directed at "immunologically functional analogues."

These claims involve a genus of materials, "immunologically functional analogues" of a defined peptide sequence. The specification defines "immunologically functional analogues" on page 9 as "modified...yet retains substantially the same secondary and tertiary structure and/or immunogenicity as the original ScoV antigenic peptide." However, the specification does not teach the secondary or tertiary structure of the disclosed peptides, nor permit one

skilled in the art to predict what changes can be made without substantially changing the immunogenicity. For example, the specification teaches on page 31 that addition of three lysine residues to SEQ ID NO:5 substantially changes the antigenic properties (albeit in a beneficial manner). Furthermore, claims 4 and 11 explicitly require sequences of SCoV isolates that were not in applicant's possession at the time, nor known in the art. Considering the scope of the genus, the fact that only one species of "analog" was reduced to practice (and that with a substantial change in properties), the unpredictable effect of sequence alterations on immunogenicity, and the limited guidance in the specification, it is concluded that the specification does not reasonably convey possession of the full scope of "analogues" recited in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 11 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Herold US 2005/0002953. In Example 9, Herold teaches a peptide which is a

deletion of 10 amino acids or less at the C-terminus of SEQ ID NO: 5, thereby meeting the claim limitations.

Claims 4-6 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hu et al (Genomics Proteomics Bionformatics 1(2): 118-130, May 2003). Hu teaches a synthetic peptide M001 which is a deletion of 2 amino acids at the C terminus of SEQ ID NO:5, and a charge modification by addition of two lysines at the N terminus, see Table 4 on page 129. Hu also teaches use of the peptide in an ELISA immunoassay to detect SCoV antibodies, see Figure 7 and Table 8 on page 124. The reference therefore meets each and every limitation of these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herold US 20050002953. Herold teaches a chemically synthesized peptide consisting of the N-terminal 15 amino acids of the SARS M protein. This differs from the peptide of SEQ ID NO:5 in being 15 amino acids long, rather than 22 amino acids long. However, the length of a synthetic peptide is a matter of design choice. Since Herold teaches the sequence of the full length M protein, use of an N-terminal 22-mer instead of an N-terminal 15-mer is seen as an obvious variation, absent unexpected results. The invention as a whole is therefore seen as prima facie obvious.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al (Genomics Proteomics Bionformatics 1(2): 118-130, May 2003). Claims 1 and 7 differ from Hu in that SEQ ID NO:s 5 and 6 contain the 22 N-terminal residues of SCoV M protein instead of 20, and in that SEQ ID NO:6 contains 3 lysine residues instead of 2 and SEQ ID NO:5 contains no lysine residues. However, given the teachings of Hu that the N-terminal 20 amino acids of M are reactive with immune serum from SARS patients, one of ordinary skill in the art would reasonably expect the N-terminal 22 amino acids to be similarly reactive, with or without a lysine tag. Therefore use of an N-terminal 22-mer instead of an N-terminal 15-mer is seen as an obvious variation, absent unexpected results. The invention as a whole is therefore seen as prima facie obvious.

Double Patenting

Claims 1-7, 11 of this application conflict with claims 1-3, 5-8, 12 of Application No. 10/983854. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/17/05

MARY E. MOSHER, PH.D
PRIMARY EXAMINER